Veterinary Medicines Directorate

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Post Authorisation Assessments

AviPro IBD Xtreme Lyophilisate for Suspension
Vm 00879/3032

•	March 2024	Increase of the maximum batch size of the bulk vaccine without process change.
•	15 December 2023	Update QRD to v9.
•	05 December 2022	The addition of four alternative manufacturers for medium 199 to the dossier quality documentation.
•	17 August 2021	Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance Deletion of a specification parameter of the finished product.
•	16 December 2020	Change of MAH from Lohmann Animal Health GmbH, Heinz-Lohmann-Straße 4, D-27472 Cuxhaven, to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	18 January 2017	Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product.
•	27 March 2015	Changes to the product literature. Updates to the dossier.
•	21 November 2014	Update to the DDPS.
•	02 May 2014	Updates made to the product labelling not connected to the SPC.
•	07 February 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	16 April 2013	Change to batch release arrangements and quality control of the finished product. Change in the test procedure for the finished product.
•	17 December 2012	Renewal procedure.
•	16 May 2012	Change in the name of the Marketing Authorisation Holder, change in the name of manufacturer of the active substance, batch release, quality control and packing.
•	09 June 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	22 December 2010	To modify the SPC and package leaflet due to pharmacovigilance data.
•	14 September 2009	To change the QPPV vaccines.